established within a 7-mile radius of Aurora State Airport, with segments extending from the 7-mile radius to 20 miles northeast and 10.9 miles northwest of the airport.

Class D and Class E airspace designations are published in paragraph 5000, 6002, and 6005, respectively, of FAA Order 7400.9Y, dated August 6, 2014 and effective September 15, 2014, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document will be published subsequently in the Order.

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish controlled airspace at Aurora State Airport, Aurora, OR.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014, is amended as follows:

Paragraph 5000 Class D airspace.

* * * * *

ANM OR D Aurora, OR [New]

Aurora, Aurora State Airport, OR
(Lat. 45°14′50″ N., long. 122°46′12″ W)
Canby, Workman Airpark, OR
(Lat. 45°12′27″ N., long. 122°40′09″ W)

That airspace extending upward from the surface to and including 2,700 feet within a 5-mile radius of Aurora State Airport, excluding that airspace below 1,300 feet beyond 3.3 miles from the airport from the 142° bearing clockwise to the 172° bearing from the airport, and the 250° bearing clockwise to the 266° bearing from the airport, and that airspace within a 0.5-mile radius of Workman Airpark, OR. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6002 Class E airspace designated as surface areas.

* * * * *

ANM OR E2 Aurora, OR [New]

Aurora, Aurora State Airport, OR
(Lat. 45°14′50″ N., long. 122°46′12″ W)
Canby, Workman Airpark, OR
(Lat. 45°12′27″ N., long. 122°40′09″ W)

That airspace extending upward from the surface to and including 2,700 feet within a 5-mile radius of Aurora State Airport, excluding that airspace below 1,300 feet beyond 3.3 miles from the airport from the 142° bearing clockwise to the 172° bearing from the airport, and the 250° bearing clockwise to the 266° bearing from the airport, and that airspace within a 0.5-mile radius of Workman Airpark, OR.

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM OR E5 Aurora, OR [New]

Aurora, Aurora State Airport, OR
(Lat. 45°14′50″ N., long. 122°46′12″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Aurora State Airport, and that airspace 1.6 miles either side of the 007° bearing from airport extending from the 7-mile radius to 20 miles northeast of the airport, and that airspace 1.2 miles either side of the 306° bearing from airport extending from the 7-mile radius to 10.9 miles northwest of the airport.

Issued in Seattle, Washington, on February 25, 2015.

Christopher Ramirez,

Acting Manager, Operations Support Group, Western Service Center, AJV–W2.

[FR Doc. 2015–05700 Filed 3–12–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 320

[Docket No. FDA–2011–N–0830]

RIN 0910–AF97

Abbreviated New Drug Applications and 505(b)(2) Applications

Correction

In Proposed Rule Document 2015–01666, pages 6801–6896, publishing in the Issue of Friday, February 6, 2015, make the following corrections:

1. On page 6807, in the second column in Table 1, the heading should read:

	Proposed Changes See section of this document (identified in parentheses) for more detailed information regarding the proposed change

2. On page 6808, in Table 1, the second column should read:

314.95(e)	Documentation of Timely Sending and Receipt of Notice of Paragraph IV Certification, including: a. Acceptable methods of sending notice of paragraph IV certification; and b. Amendment documenting timely sending and confirmation of receipt of notice of paragraph IV certification. (II.D.4).

3. On pages 6818–6819, in Table 2, the second row should read:

Current regulations	Proposed revisions to regulations
General Requirements (§ 314.53(c)(1)) Patent information will not be accepted unless it is complete and submitted on the appropriate forms (Form FDA 3542a or 3542).	*General Requirements (§ 314.53(c)(1))* • Patent information will not be accepted unless it is submitted on the appropriate forms (Form FDA 3542a or 3542) and contains the information required in § 314.53(c)(2).
Reporting Requirements (§ 314.53(c)(2)) The required information and verification in § 314.53(c)(2)(i) and (c)(2)(ii) includes: • Information on whether the patent has been submitted previously for the NDA • Information on whether the drug substance patent claims a polymorph that is the same active ingredient that is described in the pending NDA or supplement, and, if so, has test data described in § 314.53(b)(2)	*Reporting Requirements (§ 314.53(c)(2))* The required information and verification in § 314.53(c)(2)(i) and (c)(2)(ii) includes: • Information on whether the patent is a re-issued patent of a patent submitted previously for listing for the NDA or supplement. • Information on whether the drug substance patent claims *only* a polymorph that is the same active ingredient that is described in the pending NDA or supplement, and, if so, has test data described in § 314.53(b)(2).

4. On pages 6838–6839, in Table 8, the second row should read:

Current regulations	Proposed revisions to regulations
Documentation of receipt of notice (§§ 314.52(e) and 314.95(e)) • Applicant must amend its 505(b)(2) application or ANDA to document the date of receipt of the notice of paragraph IV certification by each patent owner and NDA holder provided the notice. • Applicant must include a copy of the return receipt or other similar evidence of the date the notification was received. — FDA will accept as adequate documentation of the date of receipt a return receipt or a letter acknowledging receipt by the person provided the notice. • An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance.	*Documentation of timely sending and receipt of notice (§§ 314.52(e) and 314.95(e))* • Applicant must amend its 505(b)(2) application or ANDA to provide documentation of the date of receipt of the notice of paragraph IV certification by each patent owner and NDA holder provided the notice. —FDA will accept as adequate documentation of the date of receipt a return receipt, signature proof of delivery by a designated delivery service, or a letter acknowledging receipt by the person provided notice. — Amendment must be submitted to FDA within 30 days after the last date on which notice was received by a patent owner or NDA holder. • Amendment also must include adequate documentation that notice was sent on a date that complies with the timeframe required by § 314.52(b) or (d) or § 314.95(b) or (d), as applicable. —FDA will accept a copy of the registered mail receipt, certified mail receipt, or receipt from a designated delivery service, as adequate documentation of the date of delivery. • An ANDA applicant's amendment must include a dated printout of the Orange Book entry for the RLD that includes the patent that is the subject of the paragraph IV certification. • An applicant may rely on another form of documentation only if FDA has agreed in advance.

5. On pages 6842–6843, in Table 9, the third row should read:

Current regulations	Proposed revisions to regulations
After a Finding of Infringement (§§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A)) • Change from paragraph IV certification to paragraph III certification required after a final judgment is entered finding the patent to be infringed. • Provision applies if patent infringement action initiated within 45 days of receipt of notice of paragraph IV certification.	*After a Finding of Infringement (§§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A))* • Change from paragraph IV certification to paragraph III certification required after court enters final decision from which no appeal has been or can be taken, or signs settlement order or consent decree with a finding of infringement (unless the patent also is found invalid). An applicant may instead provide a statement under § 314.50(i)(1)(iii) or § 314.94(a)(12)(iii) with respect to a method-of-use patent if the 505(b)(2) application or ANDA is amended such that the applicant is no longer seeking approval for a method of use claimed by the patent. • Provision applies if patent infringement action initiated after receipt of notice of paragraph IV certification, irrespective of whether the action is brought within the 45-day period.

6. On pages 6859–6861, in Table 12, the third, sixth, and seventh rows should read:

Current regulations	Proposed revisions to regulations
Date of approval letter (§ 314.107(b)(1)) • Except as provided in § 314.107(b)(3), (b)(4), and (c), approval will become effective on the date FDA issues an approval letter if the applicant certifies that: (i) there are no relevant patents; or (ii) the patent information has not been submitted to FDA; or (iii) the relevant patent has expired; or (iv) the relevant patent is invalid, unenforceable, or will not be infringed.	*Timing of approval based on patent certification or statement (§ 314.107(b)(1))* • If none of the reasons in § 314.125 or § 314.127 for refusing to approve the application apply, and none of the reasons in § 314.107(d) for delaying approval apply, the 505(b)(2) application or ANDA may be approved— (i) *Immediately,* if the applicant certifies that: (A) the patent information has not been submitted to FDA; or (B) the relevant patent has expired; or (C) the relevant patent is invalid, unenforceable, or will not be infringed, except as provided in § 314.107(b)(3) and (c), and the 45-day period provided for in section 505(c)(3)(C) and 505(j)(5)(B)(iii) of the FD&C Act has expired; or (D) there are no relevant patents. (ii) *Immediately,* if the applicant submits an appropriate statement explaining that a method-of-use patent does not claim an indication or other condition of use for which it is seeking approval.
Disposition of patent litigation (§ 314.107(b)(3)(i)) • (A) Except as provided in § 314.107(b)(3)(ii) through (b)(3)(iv), if — applicant submits a paragraph IV certification; and — patent owner or its representative or the exclusive patent licensee brings suit for patent infringement within 45 days of receipt by the patent owner of the notice of paragraph IV certification, Approval may be made effective 30 months after the date of the receipt of the notice of paragraph IV certification by the patent owner or by the exclusive licensee (or their representatives) unless the court has extended or reduced the period; or • (B) If the patented drug product qualifies for 5-year exclusivity, and — patent owner or its representative or the exclusive patent licensee brings suit for patent infringement during the 1-year period beginning 4 years after the date the patented drug was approved and within 45 days of receipt by the patent owner of the notice of paragraph IV certification, Approval may be made effective at the expiration of 7½ years from the date of NDA approval for the patented drug product.	*Disposition of patent litigation (§ 314.107(b)(3)(i))* • (A) Except as provided in § 314.107(b)(3)(ii) through (b)(3)(viii), if, with respect to patents for which required information was submitted before the date on which the 505(b)(2) application or ANDA was submitted to FDA (excluding an amendment or supplement), —applicant submits a paragraph IV certification; and —patent owner or the exclusive patent licensee brings suit for patent infringement within 45 days of receipt of the notice of paragraph IV certification, 505(b)(2) application, or ANDA may be approved 30 months after the later of the date of the receipt of the notice of certification by any owner of the listed patent or by the NDA holder who is an exclusive patent licensee (or their representatives) unless the court has extended or reduced the period; or • (B) If the patented drug product qualifies for 5-year exclusivity, and —patent owner or its representative or the exclusive patent licensee brings suit for patent infringement during the 1-year period beginning 4 years after the date the patented drug was approved and within 45 days of receipt of the notice of paragraph IV certification, the 505(b)(2) application or ANDA may be approved at the expiration of 7½ years from the date of NDA approval for the patented drug product.
Disposition of patent litigation (§ 314.107(b)(3)(ii)–(b)(3)(iv))	*Disposition of patent litigation (§ 314.107(b)(3)(ii)–(b)(3)(viii)*

Current regulations	Proposed revisions to regulations
If before the expiration of the 30-month period, or 7½ years where applicable: • (ii) the court issues a final order that the patent is invalid, unenforceable, or not infringed, approval may be made effective on: — the date the court enters judgment; • (iii) the court issues a final order or judgment that the patent has been infringed, approval may be made effective on: — the date the court determines that the patent will expire or otherwise orders • (iv) the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug product until the court decides the issues of patent validity and infringement, and if the court later decides that the patent is invalid, unenforceable, or not infringed, approval may be made effective on: — the date the court enters a final order or judgment that the patent is invalid, unenforceable, or not infringed.	If before the expiration of the 30-month period, or 7½ years where applicable: • (ii) the district court decides that the patent is invalid, unenforceable, or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the 505(b)(2) application or ANDA may be approved on: —(A) the date on which the court enters judgment reflecting the decision; or —(B) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed. • (iii) the district court decides that the patent has been infringed and the judgment is appealed, the 505(b)(2) application or ANDA may be approved on: —(A) the date on which the mandate is issued by the court of appeals entering judgment that the patent is invalid or not infringed; or —(B) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent is invalid or not infringed. • (iv) the district court decides that the patent has been infringed and the judgment is not appealed or is affirmed, the 505(b)(2) application or ANDA may be approved no earlier than the date specified by the district court in an order under 35 U.S.C. 271(e)(4)(A). • (v) the district court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug product until the court decides the issues of patent validity and infringement: — if the court later decides the patent is invalid, unenforceable, or not infringed, the 505(b)(2) application or ANDA may be approved per § 314.107(b)(3)(ii). —if the court decides that the patent has been infringed, the 505(b)(2) application or ANDA may be approved per § 314.107(b)(3)(iii) or (b)(3)(iv), as applicable. • (vi) the patent owner or the exclusive patent licensee (or their representatives) agrees in writing that the 505(b)(2) application or ANDA may be approved any time on or after the date of the consent, approval may be granted on or after that date. • (vii) the court enters an order requiring the 30-month or 7½-year period to be terminated, the 505(b)(2) application or ANDA may be approved in accordance with the court's order. • (viii) the court enters an order of dismissal, with or without prejudice, without a finding of infringement, the 505(b)(2) application or ANDA may be approved on or after the date of the order.

[FR Doc. C1–2015–01666 Filed 3–12–15; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–143040–14]

RIN 1545–BM59

Reporting of Original Issue Discount on Tax-Exempt Obligations; Basis and Transfer Reporting by Securities Brokers for Debt Instruments and Options

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to information reporting by brokers for transactions involving debt instruments and options, including the reporting of original issue discount (OID) and acquisition premium on tax-exempt obligations, the treatment of certain holder elections for reporting a taxpayer's adjusted basis in a debt instrument, and transfer reporting for section 1256 options and debt instruments. The text of those regulations also serves as the text of these proposed regulations.

DATES: Written or electronic comments must be received by June 11, 2015.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–143040–14), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–143040–14), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–143040–14).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Pamela Lew, (202) 317–7053; concerning submissions of comments, Regina Johnson, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: